CDRH Guidance Development Workshop

June 5, 2014

Paul Brown, Government Relations Manager
National Center for Health Research

About National Center for Health Research

(formerly National Research Center for Women & Families

- We are dedicated to improving the health and safety of adults and children by using research to support the use of more effective treatments and policies.

- We do not accept funding from the medical device or pharmaceutical industry. We do not have any financial conflicts of interest.

Consumer and Patient Perspective on How to Improve the Guidance Development Process

- **What Consumer and Patient Advocates Want**

  Like Industry, we want:

  - Clear, concise, understandable draft guidance documents.
  - Precise terms. It's not unusual for guidance documents to use terms such as "limited quantities" or "inordinate amounts."

What We Want (continued)

We want:

- A summary of the guidance document right up front. (FDA's Federal Register Notices usually have a summary why not guidance documents too)?
- The summary should be explicit enough that patient and consumer groups can quickly determine if this issue is a priority for them.

Summary Should Contain

- The purpose of the guidance document.
  - What issue or problem is it addressing?
- How the guidance document will affect the data requirements of the FDA's review of the safety and effectiveness for the device?

Summary Should Contain (Continued)

- Who requested or drafted the guidance?
  - FDA, industry, or patient and consumer advocate?
  - Was it issued to comply with a statutory deadline?
  - Was it issued to save FDA and industry resources?
- Which medical products are covered by the guidance document?

Summary Should Contain (continued)

- Is the guidance being issued as part of special controls for a device?

- What enforcement mechanisms will FDA use if a company does not follow special controls regarding safety issues?

FDA's Working Group's Recommendations

We agree with the FDA's cross-Agency Working Group's recommendations to:

- Streamline the development of guidance documents;
- Reduce the time between issuing draft and final guidance documents; and
- Make it easier to find guidance documents on FDA's website.

Guidance Documents Focused on Industry

We understand why industry is heavily involved in the guidance development process. Guidance will affect their work and their bottom line.

However, patients and consumers lives depend on these devices. Patient, Consumer , and Public Health groups that are independent of industry should also be consulted at each stage and their views should also be incorporated.

Patients and Consumer Advocates Interest Overlap with Industry's

Patients, consumers, and public health advocates should have input on safety and effectiveness issues including:

- Labeling, promotion (how will the FDA prevent off label promotion?).
- Testing of products.
  - What will FDA do if guidance is not followed?
  - Will inadequate testing be tolerated and devices cleared/approved anyway?

Safety and effectiveness issues

Patient, Consumer, and public health advocates are concerned that guidance documents seem to focus more on expedited clearances/approvals than on safety and effectiveness.

Examples from actual draft guidance documents:

- "Speed device development;
- "Enable faster development of…medical devices;"
- "Expediting their development, assessment, and review…"

Safety and Effectiveness (continued)

- Patients, consumers, and public health advocates do not want quick access to new devices that are not proven safe and effective.
- Our focus is on the FDA's key mission: protecting the public health.
- We want to know that safety and effectiveness is adequately addressed in the guidance. That is not always true. And when it is, it is not always enforced.

It's Not the Law

- Guidance documents are not legally binding.
- "Nevertheless, guidance documents are important because they assist both staff and industry in understanding FDA's current thinking on certain topics." Source: Federal Register, Volume 79, Number 87, (Tuesday, May 6 2014). Also see 21 CFR 10.115(d).
- We strongly encourage FDA to do a better job of following their guidance. Too often the safeguards in the guidance are ignored.

How important are they?

- **Writing guidance documents "can stagnate if…the [subject matter expert] SME has competing priorities, such as review responsibilities."** **Source: FDA Report on Good Guidance Practices (December 2011).**

- **If, CDRH guidances are ignored by companies and the FDA does nothing, then making the guidances seems like a waste of time.**

Not Top Priorities

- Since guidances are not always followed on patient safeguards, it should surprise few that patient and consumer stakeholders do not participate more in the development of guidance documents.
- Independent nonprofit organizations and academic researchers have limited resources to devote to FDA issues. If guidances are outdated or ignored, nonprofit groups are not going to waste their limited resources on them.

Are Too Many Guidances Being Issued?

- 47 CDRH guidance documents were recently issued in one year.
- Independent nonprofit organizations do not have the resources to review so many guidances.
- That's why a Summary statement for the guidances is so important.

Issuing of Guidance Documents Needs to Be Prioritized & Cut Back

- The Working Group noted that some guidances that are approved for development are never completed.
- Guidances should be prioritized on whether the guidance addresses a significant public health issue (as the Working Group recommended).

Brief Comments on Outreach

- **Federal Register Notices may not be the best way to inform independent patient and consumer nonprofit groups about opportunities to comment on guidances.**
- If CDRH/FDA is not already doing this, they should be proactive in signing people up for the FDA's Daily Digest Bulletin, which lists info about guidances documents in a more readable format. Even better would be a Weekly Digest Bulletin.
- Send an e-mail offering the Bulletin to any advocate who attends an FDA meeting or signs a public comment.

Conclusion

Consumer, patient, and public health advocates want many of the same things industry wants (clear and concise guidances).

We want a clear Summary included in the guidance document that lists key information.

We want clear and specific guidance relevant to safety and effectiveness (labeling, testing, and “enforcement” policies for these non-binding documents)

We want FDA to make it easier for patient, consumer, and public health advocates to be more involved.

Paul Brown
Government Relations Manager
National Center
for Health Research

pb@center4research.org
www.center4research.org